REMARKS

Claims 1-20 are currently pending in the application. Claims 1 and 11 have been amended herein for clarification purposes as noted.

Rejections of Claims 1-10 under 35 U.S.C. § 102(e)

Claims 1-10 are rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,447,530 to Ostrovsky et al. ("Ostrovsky").

As suggested by the Examiner, Claim 1 has been amended for clarification to recite, inter alia, "an implantable device, said device being movable between a reduced cross section and an enlarged cross section, said device having a proximal end and a distal end, and wherein said device, when fully unstressed, increases radially in dimension from its proximal end to an apex portion, and then decreases radially in dimension from the apex portion to the distal end, wherein the apex portion has the largest radial diameter of any portion of the device. . ."

Applicants note that proper written description support for this amendment can be found, for example, in Figures 30, 30A, 34A, 34B, and paragraph [0106] of the disclosure. As described in paragraph [0106] of the specification and shown in the aforementioned figures, each support 228 of device 10 comprises a proximal spoke portion 218, a distal spoke portion 217, and an apex 220. Each aforementioned portion may be a region on an integral support 228 which extends in a generally curved configuration as illustrated with a concavity facing toward the longitudinal axis of the occlusion device, in other words indicating that the apex portion has the largest radial diameter of the device. Figures 30, 30A, 34A, and 34B also show the deployed device, increasing radially in dimension from its proximal end to an apex portion, which as shown has the largest radial diameter of any portion of the device, and then decreasing radially in dimension from the apex portion to the distal end.

Although Applicants do not agree with the rejections, Claim 1 has been amended herein for clarification purposes, and the amendment is fully supported, as noted above. Applicants respectfully submit that Ostrovsky fails to identically teach or suggest, every element of Claim 1, as amended herein. See M.P.E.P. § 2131 (stating that in order to anticipate a claim, a prior art reference must identically teach every element of the claim).

The Examiner found that Ostrovsky teaches an implantable device that, as shown in Fig.

29 "expands from either end to an apex in the middle. The apex is formed at the points where 202 and 208 cross" (Office Action, p. 6). As the Examiner acknowledges, "the claim language does not restrict the apex to be the largest diameter of any portion of the filter. The fact that 202 and 208 extend past the apex is not relevant since the claims do not exclude the existence of this structure." Applicants note that the point in Fig. 29 of Ostrovsky found by the Examiner to be the apex is not the portion that has the largest radial diameter of the device. When fully unstressed and deployed within a blood vessel, Applicants note Ostrovsky's device as shown in Fig. 29, fails to teach or suggest every element recited in amended Claim 1; therefore Claim 1 is not anticipated by Ostrovsky. We thus request that the Examiner withdraw this rejection. Applicants note that Claims 2-10 depend from Claim 1 and contain all of the limitations thereof in addition to further distinguishing features; thus Applicants submit that these claims are in condition for allowance as well.

Rejections of Claims 1-10 under 35 U.S.C. § 103(a)

The Examiner also rejected Claims 1-10 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 4,619,246 to Molgaard-Nielsen et al. in view of Ostrovsky. Applicants respectfully submit that the Examiner has not supplied the requisite motivation to combine Molgaard-Nielsen's disclosure with that of Ostrovsky. Applicants note that "[t]he showing of a motivation to combine must be ***clear and particular***, and it must be supported by ***actual evidence***." *In re Dembiczak*, 50 U.S.P.Q.2d 1614, 1617 (Fed. Cir. 1999) (*emphasis added*). In place of a "clear and particular" suggestion, the Examiner argues that "it would have been obvious to have implanted the filter of [Molgaard-Nielsen] with the device of Ostrovsky, as this implantation mechanism would allow for the movement of the inner catheter relative to the body lumen without irritation and would allow for the filter to be held by the hook until properly positioned" Office Action at p. 5.

Such broad, conclusory statements by the Examiner are neither "actual evidence" that the skilled artisan would be motivated to modify Molgaard-Nielsen to use the deployment mechanism of Ostrovsky, nor do such statements suggest that such a combination would work. It does not follow that, because a method is known and desirable in one context, the method is, therefore, necessarily suggested for combination with every known reference with which

combination would be possible regardless of context. In other words, citing the known, general advantages of the deployment elements of Ostrovsky (and not providing more) does not mean that an adequate suggestion or motivation automatically exists to combine Molgaard-Nielsen's disclosure with Ostrovsky's or that there would be an expectation of success in such a combination. Applicants assert that the Examiner's rejections rest upon the forbidden "obvious to try" test of obviousness, rather than being supported by a clear and particular suggestion or motivation for the skilled artisan to combine Molgaard-Nielsen with Ostrovsky, as required. *In re Geiger*, 2 U.S.P.Q.2d 1276, 1278 (Fed. Cir. 1987) and an expectation of success. Therefore, Applicants submit that a *prima facie* case of obviousness has not been made.

Furthermore, the suggestion proffered by the Examiner is inadequate to motivate the skilled artisan to modify Molgaard-Nielsen with Ostrovsky's deployment system to include a sheath and a deployment catheter as claimed. Molgaard-Nielsen neither teaches nor suggests a separate sheath, and furthermore only discloses utilizing a solitary delivery catheter. For example, the Molgaard-Nielsen disclosure states that "legs 6 [of the filter] will normally be made of the same or a similar material as wires 2 so that they can be readily collapsed to fit within the lumen of the *insertion catheter*, and spring back to engage the wall of the blood vessel when released from the *catheter*. The pronounced S-shape of legs 6 in the region immediately inwardly of hooks 7 ensures that when the filter basket moves through the catheter it will be the *smooth curved portions of the legs rather than the hooks which contact the catheter wall*,"(col. 3, ll. 24-33). Nowhere in the reference is it taught or suggested that a sheath as disclosed in Applicant's device could overcome the problem of hooks causing damage to the catheter or to body tissue; and in fact the S-shape design of legs 6 in Molgaard-Nielsen's filter is a distinctly alternative solution, specifically to ensure that the smooth curved portions of the legs rather than the hooks contact the catheter wall. Furthermore, the device of Molgaard-Nielsen "may readily be received within a *No. 10 French catheter* when collapsed. For this purpose, the interior of basket 21 may be pre-filled by a suitable embolization agent following which the basket is inserted in a *catheter* which subsequently is introduced subcutaneously to deliver the basket at the appropriate location" (col. 3, ll. 42-44), further indicating that it is contemplated that a deployment catheter without a sheath be utilized for deployment of the Molgaard-Nielsen device. Applicants submit that one of ordinary skill in the art would not be motivated to use the *specific* deployment

elements disclosed by Ostrovsky to deliver Molgaard-Nielsen's device. On this point, the Federal Circuit has ruled that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." *In re Fritch* at 1784. In order to avoid using Applicants' disclosure as a blueprint to pick and choose certain elements, while ignoring others, the Examiner must supply a clear and particular motivation or suggestion to do so. Otherwise, the Examiner's true motivation is forbidden hindsight.

The Examiner has not shown such a suggestion. The Examiner must show that the skilled artisan would be motivated to specifically select Molgaard-Nielsen's filter for combination with Ostrovsky's deployment system with an outer catheter, inner catheter, and tether, despite Molgaard-Nielsen's failure to teach any particular advantages of a deployment system with elements such as those described in Ostrovsky's. The Examiner has not shown that the skilled artisan would be motivated to select Ostrovsky's deployment components with Molgaard-Nielsen's device and can only be applying an "obvious to try" standard.

Rejection of Claims 11-20 under 35 U.S.C. § 103(a)

The Examiner rejected Claims 11-20 under 35 U.S.C. § 103(a) as being unpatentable over Ostrovsky in view of Brooks et al (U.S. Patent No. 6,346,116 B1) ("Brooks") and Tsugita et al. (U.S. Patent No. 5,911,734) ("Tsugita"). Claims 11-20 are also rejected as unpatentable over Molgaard-Nielsen in view of Ostrovsky, Tsugita, and Brooks.

Claim 11 has been amended for clarification to recite, inter alia, "an adjustable device deployment system, for implanting an implantable device within an atrial appendage comprising . . . a deployment line adapted to extend through the deployment catheter releasably attached to the implantable device, wherein the implantable device is moveable between its reduced cross section wherein the device is not in contact with body tissue and its enlarged cross section wherein the device engages the inner surface at the atrial appendage, the implantable device configured to move from its reduced cross section to its enlarged cross section by actuation of the deployment line while substantially maintaining an axial position of at least one of the proximal and distal ends of the implantable device relative to the atrial appendage, and wherein the implantable device is configured to move from its reduced cross section to its enlarged cross section while the proximal end of the implantable device is distal to the distal end of the

deployment catheter by actuation of the deployment line while the implantable device is outside of any catheter or tube."

Applicants note that proper written description support for this amendment can be found, for example, in Figs. 33, and paragraph [0110] of the disclosure. In one embodiment, actuating the deployment line 240, such as by proximal retraction as described, will cause the distal hub 191 to be drawn toward the proximal hub 222, thereby radially enlarging the cross-sectional area of the occlusion device 10. (see paragraph [0110]). In this manner, the claimed device's movement from the reduced to the enlarged cross section can occur while at least one of the proximal and distal ends substantially maintains an axial position relative to a fixed point, such as the atrial appendage. The transformation process as claimed does not at all require the device in its reduced cross section to contact body tissue, such as a body lumen of a size to restrict the expansion of the filter. Furthermore, as clearly illustrated in Fig. 33, when the deployment line is actuated, for example, when two hubs 191, 222 are drawn together using the loop 244 as described in paragraph [0110], it is apparent that the claimed device is movable between a reduced cross section wherein the device is not in contact with body tissue and an enlarged cross section wherein the device engages, for example, the inner surface at the atrial appendage (of which the inner surface is shown in Figs. 11-12), while the device is outside of any catheter, including deployment catheter 238 shown in Fig. 33, and trans-septal catheter 81 (shown in Fig. 9 and located proximal relative to deployment catheter 238), or other tube that could restrict expansion of the device.

The Examiner found that Ostrovsky discloses the invention as claimed with the exception of the material of the filter having a membrane and the material of the membrane being ePTFE. Also, the Examiner states that Molgaard-Nielsen as modified by Ostrovsky makes obvious the invention as claimed, with the exception of the barrier and filter material. Tsugita discloses a filter with a membrane; and that it would have been obvious to have placed a membrane on the filter of Ostrovsky. The Examiner further alleges that this provides an effective means to filter out undesirable particles while allowing blood-flow therethrough, and placing the membrane on the proximal face of the filter as taught by Tsugita will allow the interior of the mesh to be directed upstream to collect debris if introduced in a retrograde orientation. Furthermore,

Examiner states it would have been obvious, as in Claim 15, to use ePTFE as the filter material as disclosed in Brooks.

Although Applicants do not agree with the rejections, Claim 11 has been amended herein for clarification purposes, and the amendment is fully supported, as noted above. Applicants request that the obviousness rejection be withdrawn because none of the cited references teaches or suggests all of the recited claim limitations of Claim 11, as amended. Furthermore, Applicants submit that one of ordinary skill of the art would have no motivation to produce the claimed features of the present application from either reference cited. See M.P.E.P. § 2143.

Ostrovsky discloses that the steps of the removal process in reverse would provide a method of placing a filter 200 in a vessel, as shown in Figs. 29-35 (col. 10, ll. 49-56). While the Examiner found that Ostrovsky's filter "can indeed enlarge from the reduced configuration to the expanded configuration by actuation of the deployment line when outside any catheter, as the filter when expelled outside of the catheter or sheath could be placed into a body lumen of a size to restrict the expansion of the filter, and then upon either pushing or pulling by the deployment line could indeed cause the filter to enter a larger portion of the body lumen and cause the filter to assume its expanded configuration." (Office Action, p. 6). Applicants submit that Ostrovsky's device is not configured to move as recited in amended Claim 11, from its reduced cross section to its enlarged cross section by actuation of the deployment line while substantially maintaining an axial position of at least one of the proximal and distal ends of the implantable device relative to the atrial appendage, and wherein the implantable device is configured to move from its reduced cross section to its enlarged cross section while the proximal end of the implantable device is distal to the distal end of the deployment catheter by actuation of the deployment line while the implantable device is outside of any catheter or tube. Applicants further submit that Molgaard-Nielsen's device also cannot move as claimed (e.g., col. 1, ll. 63-col. 2. l. 2, col. 3, ll. 25-28). Neither Tsugita nor Brooks make up for this deficiency. Therefore, the references cited, even when combined, do not teach or suggest all of the limitations of amended Claim 11.

In light of the above, Applicants assert that Claim 11 is not obvious in view of the prior art references, and respectfully request that the Examiner withdraw this rejection. Applicants also note that Claims 12-20 depend from Claim 11 and contain all of the limitations thereof in

addition to further distinguishing features; thus Applicants submit that they are in condition for allowance as well.

CONCLUSION

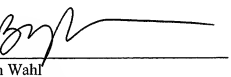
For the reasons presented above, Applicants submit that the present application is in condition for allowance and respectfully request the same. If any issues remain, the Examiner is cordially invited to contact Applicants' representative at the number provided below in order to resolve such issues promptly.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 11-1410.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 4/24/07

By: 

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